

**REMARKS:**

In response to the Office Action mailed August 14, 2002, claims 70, 79, and 82 have been amended.

In the Office Action, claims 70-75, 78, 79, and 81 were rejected under 35 U.S.C. § 102(e) as anticipated by U.S. Patent No. 5,460,628 ("the Neuwirth et al. reference") and claims 82 and 84 were rejected under 35 U.S.C. § 102(e) as anticipated by U.S. Patent No. 5,498,238 ("the Shapland et al. reference"). In addition, claims 76 and 80 were rejected under 35 U.S.C. § 103(a) as being unpatentable over the Neuwirth et al. reference in view of the Shapland et al. reference and claim 83 was rejected under 35 U.S.C. § 103(a) as being unpatentable over the Shapland et al. reference. Finally, claim 82 was rejected under the judicially created doctrine of double patenting over claim 1 of U.S. Patent No. 5,902,328.

Because neither of the cited references, either alone or in combination, discloses, teaches, or suggests the subject matter of the present claims, reconsideration and withdrawal of the rejections is respectfully requested.

First, with respect to the judicially created doctrine of double patenting rejection, Applicants submit herewith a Terminal Disclaimer, disclaiming the terminal part of any patent granted on the present application that would extend beyond the expiration date of U.S. Patent No. 5,902,328. Therefore, the double patenting rejections should be withdrawn.

Turning to the § 102(e) rejections, the Neuwirth et al. reference discloses a distendable bladder 5 attached to rigid tubing 3 for effecting necrosis of endometrial tissue. (Col. 5, lines 13-17). A heating element 44 is located within the bladder 5 that includes a heating element coil 47 that

heats fluid 25 that contacts the coil 47. (Col. 6, line 67 through col. 7, line 11). During use, the applicator is inserted through the cervix into the uterus, and fluid is injected to inflate the bladder to ensure firm contact with the tissue being necrosed. (Col. 5, lines 14-28). Once the bladder is filled, access to the fluid system is closed off such that the fluid is non-circulating during the heating portion of the procedure. (Col. 10, lines 24-29).

Turning to the present claims, claim 70 recites a catheter, an expandable member disposed on the distal portion of the catheter, and an RF electrode on the distal portion and communicating with the lumen, the electrode configured for coupling to a source of RF energy, whereby RF energy may be transferred from the electrode to selected tissue areas in a patient's body via electrolyte fluid delivered through the lumen and into the interior region of the expandable member.

The Neuwirth et al. reference fails to disclose, teach, or suggest an RF electrode, as claimed. In contrast, the Neuwirth et al. reference discloses a heating coil that is heated as electrical current is delivered through it, thereby heating surrounding fluid. Such a heating coil does not transfer RF energy to the surrounding fluid nor to selected tissue, as does the claimed RF electrode. Accordingly, claim 70 and its dependent claims are neither anticipated nor otherwise obvious in light of the Neuwirth et al. reference.

Turning to the Shapland et al. reference, an angioplasty and phoretic drug delivery catheter is disclosed that includes a catheter body 11 with a permeable balloon 26 thereon and an electrode 31 on or within the catheter body 11. (Col. 8, lines 15-20). The electrode 31 is coupled to a source of direct current to promote iontophoretic movement of ionic molecules of a drug or fixative across the balloon wall. (Col. 8, lines 21-28; Fig. 6). Thus, the Shapland et al. reference also fails to disclose,

teach, or suggest an RF electrode, as claimed, a feature that is also wholly absent from the Neuwirth et al. reference. Therefore, claim 70 and its dependent claims are also not obvious in light of the combined teachings of the cited references.

Turning to claim 79, a method for ablating body tissue is recited that includes inserting a distal portion of a tubular member into the patient's body, the distal portion including an expandable member in a collapsed condition and an electrode within an interior space of the expandable member; positioning the distal portion of the tubular member proximate a target site; directing electrolyte fluid through the lumen of the tubular member and into the interior space of the expandable member; and energizing the electrode with electrical energy, thereby transferring electrical energy from the electrode through the expandable member via the electrolyte fluid to ablate the target site.

Neither of the cited references teaches or suggests transferring electrical energy from an electrode through an expandable member via electrolyte fluid to ablate tissue, as claimed. The Neuwirth et al. reference discloses heating fluid using a heating coil, while the Shapland et al. reference discloses using direct current for iontophoretic drug delivery. Accordingly, claim 79 and its dependent claims are neither anticipated nor otherwise obvious in light of the cited references.

Finally, claim 82 recites an apparatus for ablating body tissue using radio frequency (RF) energy that includes a source of RF energy, a catheter, a porous member attached to the distal portion of the catheter and defining an interior region, and an electrode disposed in the interior region and coupled to the source of RF energy.

As explained above, neither of the cited references discloses, teaches, or suggests a source of RF energy nor an electrode coupled to such a source. Further, even if the Neuwirth et al. reference could somehow be interpreted to disclose a source of RF energy, the Neuwirth et al. reference fails to teach or suggest a porous member. In fact, the Neuwirth et al. reference expressly teaches against a porous member, requiring that the disclosed bladder be nonporous such that fluid therein is noncirculating during the heating portion of the disclosed procedure. Thus, it would not be obvious to substitute the porous member of the Shapland et al. reference for the nonporous bladder disclosed in the Neuwirth et al. reference. Accordingly, claim 82 and its dependent claims are also neither anticipated nor otherwise obvious in light of the cited references.

In view of the foregoing, it is submitted that the claims presented in this application define patentable subject matter over the cited prior art. Accordingly, reconsideration and allowance of the application is requested.

Respectfully submitted,

BINGHAM McCUTCHEN LLP

Dated: November, 2002

By:



William A. English  
Reg. No. 42,515  
Attorneys for Applicants

Bingham McCutchen LLP  
Three Embarcadero Center, 18<sup>TH</sup> Floor  
San Francisco, California 94111  
Tel: (415) 393-2000  
Fax: (415) 393-2286

**VERSION WITH MARKINGS SHOWING CLAIM AMENDMENTS:**

70. (amended) An apparatus for ablating body tissue using radio frequency (RF) energy, comprising:

a catheter having a proximal portion attachable to a source of electrolyte fluid, a distal portion sized for insertion into a patient's body, and a lumen for delivering fluid from the proximal portion to the distal portion;

an expandable member disposed on the distal portion of the catheter, the expandable member defining an interior region in communication with the lumen; and

an RF electrode on the distal portion and communicating with the lumen, the electrode configured for coupling to a source of RF energy, whereby RF energy may be transferred from the electrode to selected tissue areas in a patient's body via electrolyte fluid delivered through the lumen and into the interior region of the expandable member.

79. (amended) A method for [the] ablating body tissue, comprising:  
inserting a distal portion of a tubular member into the patient's body, the distal portion comprising an expandable member in a collapsed condition and an electrode within an interior space of the expandable member;

positioning the distal portion of the tubular member proximate a target site;

directing electrolyte fluid through the lumen of the tubular member and into the interior space of the expandable member; and

energizing the electrode with electrical [ablation] energy, thereby transferring electrical [ablation] energy from the electrode through the expandable member via the electrolyte fluid to ablate the target site.

82. (amended) An apparatus for ablating body tissue using radio frequency (RF) energy, comprising:

a source of RF energy;

a catheter having a proximal portion attachable to a source of electrolyte fluid, a distal portion sized for insertion into a patient's body, and a lumen for delivering fluid from the proximal portion to the distal portion;

a porous member attached to the distal portion of the catheter, the porous member defining an interior region in communication with the lumen, the interior region capable of receiving electrolyte fluid delivered from the proximal portion of the catheter; and

an electrode disposed in the interior region and [configured for coupling to a] coupled to the source of RF energy.